K100861

JUN 17 2010

510(k) SUMMARY

Optovue's RTVue with Software 5.0

General Information

Manufacturer:

Optovue, Inc.
45531 Northport Loop West,
Fremont, CA 94538
Phone: (510) 623-8868
Fax: (510) 623-8668
Registration No.: 3005950902

Contact Person:

Azimun Jamal
Regulatory Manager
Optovue, Inc.
Phone: (510)623-8868 x188
e-mail: azimun_jamal@optovue.com

Device Information

Classification: Class II

Trade Name: RTVue with Software 5.0

Common Name: Optical Coherence Tomography (OCT)

Classification Name: Ophthalmoscope, a-c powered (21 CFR§ 886.1570)

Predicate Device

(1) RTVue (K062552) – Manufactured by Optovue, Inc
(2) CA (K071250) – Manufactured by Optovue, Inc

Purpose of the Special 510(k) notice.

The RTVue with Software 5.0 is a modification to RTVue.

Intended Use

The RTVue with Software 5.0 is an optical coherence tomography system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disk as an aid in the diagnosis and management of retinal diseases.

Device Description

The RTVue is a computer controlled ophthalmic imaging and measurement system that employs optical coherence tomography to image and measure the posterior segment of the eye. The device is currently cleared for in vivo imaging and measurement of the various retinal layers (K062552). Imaging and measurements include but are not limited to the internal limiting membrane (ILM), the retinal nerve fiber layer (RNFL), the ganglion cell complex (GCC), the retinal pigment epithelium (RPE), the outer retinal thickness, the total retinal thickness and optic disk structures including the cup and neuroretinal rim as an aid in the diagnosis and management of retinal disease. The measurements for the ILM and RPE are height measurements relative to the RPE reference plane. The RNFL, GCC, the outer retinal thickness and total retinal thickness are thickness measurements where RNFL is the thickness of the RNFL layer, the GCC is the thickness from the ILM to the inner plexiform layer (IPL), the outer retinal thickness is the thickness from the IPL to the RPE, and total retinal thickness is the thickness from the ILM to the RPE. The current submission, RTVue with Software 5.0, is for minor software modifications, such as such as scan name changes, scan length limits, marking and labeling conventions, and improved data acquisition/archiving speeds.

Substantial Equivalence

RTVue with Software 5.0 has the same intended use and indications, principles of operation, and technological characteristics as RTVue. The minor differences in the RTVue with Software 5.0 do not raise any new questions of safety or effectiveness. Thus, the RTVue with Software 5.0 is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

JUN 17 2010

Optovue, Inc
c/o Ms. Azimun Jamal
Manager of Quality/Regulatory
45531 Northport Loop W.
Fremont, CA 94538

Re: K100861
Trade/Device Name: RTVue with Software 5.0
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: HLI
Dated: May 19, 2010
Received: May 20, 2010

Dear Ms. Jamal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K100861

Device Name: RTVue with Software 5.0

Indications for Use:

The RTVue with Software 5.0 is an optical coherence tomography system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disk as an aid in the diagnosis and management of retinal diseases.

Prescription Use ✓ AND/OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Per 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K100861